UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,349	12/06/2000	Sreekant Nadkarni	01-678	9200

7590 07/17/2003

Pharmacia Corporation
Patent Department Central, 1820
P.O. Box 5110
Chicago, IL 60680-5110

EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/17/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/731,349	NADKARNI ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment of 27 February 2003, as well as the applicant's supplemental amendment of 09 June 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 18 under 35 U.S.C. 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, and Bagchi *et al.* is rendered moot with the cancellation of that claim.

The rejection of Claims 1, 3, 5-7, 9, and 10 under 35 U.S.C. 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, and Bagchi *et al.* is maintained.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, and Bagchi *et al.*

The Black application teaches synthesis of 2-(3,5-difluorophenyl)-3-(4-(methylsulfonyl) phenyl)-2-cyclopenten-1-one, a COX-2 inhibitor, and its formulation into a pharmaceutical composition by wet granulation techniques (See Methods A through C and Examples 1 through 2c, all on Pages 11-19). Uses of a composition comprising 2-(3,5-difluorophenyl)-3-(4-

(methylsulfonyl) phenyl)-2-cyclopenten-1-one through oral administration, preferably in a once- or twice-a-day treatment are also discussed, as well as the various conditions that such treatment could alleviate (See Page 3, Lines 8-10 and 29-46; and Page 5, Lines 22-29). Specific dosages, ranging from 10 mg to 250 mg, are discussed as well (See Page 5, Line 30 to Page 6, Line 5).

The Black document does not explicitly disclose the exact intended functions of the individual excipients used in the COX-2 inhibitor formulation. Black is silent with respect to the use of valdecoxib in the composition, to the limitation regarding particle size of valdecoxib, and to the specific bioavailbility features of a valdecoxib composition.

The Patel *et al.* patent describes a wide variety of formulations for solid carriers of drugs (See Abstract). Patel *et al.* teaches that various hydrophobic drugs that may be used in the disclosed solid carriers, including COX-2 inhibitors, analgesics, and opioid analgesics, alone or in mixtures thereof (See Column 5, Lines 1-23). A listing of suitable additives is given, including lubricants such as magnesium stearate; binders such as polymeric cellulose derivatives and pre-gelatinized starch; diluents such as lactose and microcrystalline cellulose, and disintegrants such as croscarmellose sodium (See Columns 39-40).

The Guess *et al.* patent is relied upon as a teaching reference, solely in order to illustrate that valdecoxib is known in the prior art, as being among a group of selective COX-2 inhibitors (See Column 33, Lines 17-20).

It would be obvious to one of ordinary skill in the art at the time the invention was made, to combine the teachings of Black, Patel *et al.*, and Guess *et al.* into the invention of the instant application. Black teaches compositions with specific COX-2 inhibitors as the active substance, along with suitable dosages. The benefit of a COX-2 inhibitor composition in a once-a-day

formulation is explained as well. Black also teaches how such COX-2 inhibitor compositions could be used to provide treatment for conditions such as rheumatoid arthritis and osteoarthritis. Patel *et al.* teach the functions of the various excipients used in the COX-2 compositions disclosed in Black. Additionally, it provides functional equivalency between the cellulosic polymer used as a binder in the formulations disclosed in Black with the pre-gelatinized starch claimed by the applicant. An examination of those formulations disclosed in Black will reveal that the quantities of the excipients lie within the ranges presented in Claim 5 (See Black; Examples 2, 2b, and 2c). It is the position of the examiner that the limitations in Claims 1 and 3 drawn to bioavailability features of the claimed invention do not impart a patentably distinct property to the claimed invention. Bagchi *et al.* give a broad teaching regarding the importance of reliable bioavailability in the administration of a drug. In the case of drugs of poor water solubility, such as COX-2 inhibitors as disclosed by Patel *et al.*, bioavailability can be improved by decreasing particle size, thereby increasing the total drug particle surface area. Bagchi *et al.*, used here as a teaching reference, also disclose that based on the available technology at the time, particle sizes ranging from as low as about 1 micron to about 50 microns may be achieved (See Bagchi *et al.*; Column 1, Lines 10-45). Hence, Bagchi *et al.* disclose merely one way, and the motivation to do so, in which one of ordinary skill in the art can make adjustments in the formulation of drug compositions in order to achieve the desired bioavailability of the active ingredient. It is the position of the examiner that the selection of suitable drug particle sizes, down to particle size ranges claimed by the applicant using technology disclosed in Bagchi *et al.*, for the purpose of manipulating the bioavailability of an active ingredient, is within the purview of one of ordinary skill in the art at the time the claimed invention was made.

The rejection of Claim 8 under 35 U.S.C. 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, Bagchi *et al.*, and Burch *et al.* is maintained.

The rejection of Claims 11-17 under 35 U.S.C. 103(a) as being unpatentable over Black in view of Patel *et al.*, Guess *et al.*, Bagchi *et al.*, and Ansel *et al.* is rendered moot with the cancellation of those claims.

Thus the invention, as a whole, is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 27 February 2003 have been fully considered but they are not persuasive. The conclusions to which the applicants arrive with regard to the invention produced by the combined disclosure of the prior art would require a narrow interpretation of both the prior art as well as the claims. The open language of Claim 1, as embodied in the use of the word "comprising" allows for the inclusion of additional components and excipients. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

The applicant has structurally the defined the instantly claimed compositions in broad terms, and only in a dependent claim. Instead, in Claim 1, the independent composition claim, the applicant has defined the instantly claimed composition in terms of bioavailability

characteristics. The applicant has not clearly stated why these characteristics could not be obtained by one of ordinary skill in the art through routine experimentation, at the time the instantly claimed invention was made. As such, the instantly claimed invention cannot be found patentable above the collective disclosure of the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
July 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600